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| <h1>TRANSMITTAL FORM</h1> <p><i>(to be used for all correspondence after initial filing)</i></p> | Application Number   | 10/079,068               |           |
|  | Filing Date          | 02/20/2002               |           |
|  | First Named Inventor | Giorgio Trinchieri et al |           |
|  | Group Art Unit       | 1646                     |           |
|  | Examiner Name        | S. Prasad                |           |
| Total Number of Pages in This Submission   |                      | 8                        |           |
|  |                      | Attorney Docket Number   | WST85BUSA |

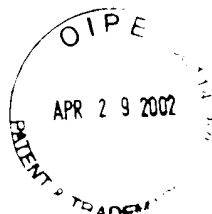
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|--|---|
| Firm or Individual name                    | Mary E. Bak, Esquire<br>Howson and Howson |
| Signature                                  | <i>Mary E. Bak</i>                        |
| Date                                       | <i>April 18 2002</i>                      |

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of ) Group Art Unit 1646  
)  
Giorgio Trinchieri et al ) Examiner S. Prasad  
)  
Appln No 10 079,068 )  
)  
Filed February 20, 2002 )  
)  
For METHODS AND COMPOSITIONS FOR ) April 18, 2002  
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INFORMATION DISCLOSURE STATEMENT

Sir

Applicants submit to the Examiner the attached Form PTO SB 08A-B document listing and this paper pursuant to 37 CFR §1.56 and § 1.97-1.98 Form PTOSB 08A-B and this paper identify documents previously cited in the parent application, U S Patent Application No. 09 395,038, filed September 13, 1999, which is currently pending.

CERTIFICATE UNDER 37 CFR 1.58a

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Debra N. Gerstemeier

According to 37 CFR § 1.98(d), Applicants have not enclosed copies of any U.S. patents, publications or other documents listed herein, which listed items were previously cited by or submitted to the United States Patent and Trademark Office in parent U.S. Patent Application No. 09/395,038, filed September 13, 1999 (pending). The parent patent application is relied upon herein for an earlier priority date under 35 USC §120.

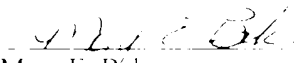
This Information Disclosure Statement is submitted within three months of the filing date of this application, and prior to receipt of an Office Action on the merits. Therefore, no fees are believed due. However, the Director of the U.S. Patent and Trademark Office is hereby authorized to charge any deficiency in any fees due with the filing of this paper or credit any overpayment in any fees paid on the filing, or during prosecution of this application to Deposit Account No. 08-3040.

The Examiner is respectfully requested to consider the documents identified in this paper and in the attached Form PTO SB/08A/B during the course of the examination of this application.

Respectfully submitted,

HOWSON AND HOWSON  
Attorneys for the Applicants

By

  
Mary E. Bak  
Registration No. 31,215  
Spring House Corporate Center  
Box 457  
Spring House, PA 19477  
Telephone (215) 540-9206  
Telefacsimile (215) 540-5818

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| INFORMATION DISCLOSURE<br>STATEMENT BY APPLICANT<br>(use as many sheets as necessary) |   |   |   | Complete if Known    |                          |                        |           |
|   |   |   |   | Application Number   | 10 079,068               |                        |           |
|   |   |   |   | Filing Date          | February 20, 2002        |                        |           |
|   |   |   |   | First Named Inventor | Giorgio Trinchieri et al |                        |           |
|   |   |   |   | Group Art Unit       | 1646                     |                        |           |
|   |   |   |   | Examiner Name        | S Prasad                 |                        |           |
| Sheet   | 1 | 2 | 3 | 4                    | 5                        | Attorney Docket Number | WST85BU5A |

| U.S. PATENT DOCUMENTS          |                       |                      |                                   |   |  |   |
|--------------------------------|-----------------------|----------------------|-----------------------------------|---|--|---|
| Examiner Initials <sup>1</sup> | Cite No. <sup>2</sup> | U.S. Patent Document |                                   | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|                                |                       | Number               | Kind Code <sup>3</sup> (if known) |   |  |   |
|                                | AA                    | 5,457,038            | B1                                | G Trinchieri                                    | 10/10/1995                                       | <b>RECEIVED</b><br><b>MAY 01 2002</b><br><b>TECH CENTER 1600 2900</b>     |
|                                | AB                    | 5,571,515            | B1                                | P Scott   | 11/05/1996                                       |   |
|                                | AC                    | 5,723,127            | B1                                | P Scott   | 03/03/1998                                       |   |
|                                | AD                    | 5,976,539            | B1                                | P Scott   | 11/02/1999                                       |   |
|                                |                       |                      |                                   |   |  |   |

| FOREIGN PATENT DOCUMENTS       |                       |                         |                     |                                   |   |  |   |    |
|--------------------------------|-----------------------|-------------------------|---------------------|-----------------------------------|---|--|---|----|
| Examiner Initials <sup>1</sup> | Cite No. <sup>2</sup> | Foreign Patent Document |                     |                                   | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | 1* |
|                                |                       | Office <sup>3</sup>     | Number <sup>4</sup> | Kind Code <sup>5</sup> (if known) |   |  |   |    |
|                                | AL                    | WO                      | WO90 05147          | A1                                | G Trinchieri                                    | 05/17/1990                                       |   |    |
|                                | AM                    | WO                      | WO94 01139          | A1                                | F Ledley  | 01/20/1994                                       |   |    |
|                                |                       |                         |                     |                                   |   |  |   |    |
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<sup>1</sup> Include citation designation number. (See attached Kinds of U.S. Patent Documents.) Enter Office that issued the document, by the two-letter code (WIPO Standard S1.3). <sup>2</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>3</sup> Kind of document by the appropriate symbol as indicated in the document under WIPO Standard S1.3. If possible, if Applicant is to place a check mark here if English language translation is attached.

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| Substantiated Form 144-A PTO<br>INFORMATION DISCLOSURE<br>STATEMENT BY APPLICANT<br>(use as many sheets as necessary) |   |    | Complete if Known    |                        |           |
|   |   |    | Application Number   | 10 079,068             |           |
|   |   |    | Filing Date          | February 20, 2002      |           |
|   |   |    | First Named Inventor | Giorgio Trinchieri     |           |
|   |   |    | Group Art Unit       | 1646                   |           |
|   |   |    | Examiner Name        | S. Prasad              |           |
| Sheet   | 2 | of | 5                    | Attorney Docket Number | WST85BU5A |

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| OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS |           |  |    |
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| Examiners Initials*                               | Cite No.† | Include name of the author (in CAPITAL LETTERS); title of the article (when appropriate); title of the item (book, magazine, journal, serial, symposium, catalog, etc.); date; page(s); volume-issue number(s); publisher, city and/or country where published | 12 |
|   | AR        | E VOEST et al. "Inhibition of Angiogenesis in Vivo by Interleukin 12", J Natl. Cancer Inst., 87 5813 (April 19, 1995)  |    |
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|   | AV        | R GAZZINELLI et al. "Interleukin-12 is Required for the T-lymphocyte-Independent Induction of Interferon $\gamma$ by an Intracellular Parasite and Induces Resistance in T-cell-deficient Hosts", Proc. Natl. Acad. Sci. USA, 90 6115 (July, 1993)             |    |
|   | AW        | G MULLER et al. "IL-12 as Mediator and Adjuvant for the Induction of Contact Sensitivity in Vivo", J. Immunol., 155 4661 (November 15, 1995)   |    |
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|   |   |    |   | Application Number     | 10 079,068         |
|   |   |    |   | Filing Date            | February 20, 2002  |
|   |   |    |   | First Named Inventor   | Giorgio Trinchieri |
|   |   |    |   | Group Art Unit         | 1646               |
|   |   |    |   | Examiner Name          | S. Prasad          |
| Sheet   | 3 | of | 5 | Attorney Docket Number | WST85BUSA          |

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| OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS |          |   |    |
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| Examiners Initials*                                | Cite No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume(s)-issue number(s), publisher, city and/or country where published | 11 |
|  | AAR      | J. ORANGE et al, "Effects of IL-12 on the Response and Susceptibility to Experimental Viral Infections", J. Immunol., 152:1253 (February 1, 1994)   |    |
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|  | AAZ      | C. HUNTER et al, "Studies on the Role of Interleukin-12 in Acute Murine Toxoplasmosis", Immunol., 84:16 (January, 1995)   |    |

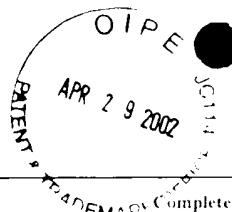
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|   |   |    |   | Application Number     | 10 079,068               |
|   |   |    |   | Filing Date            | February 20, 2002        |
|   |   |    |   | First Named Inventor   | Giorgio Trinchieri et al |
|   |   |    |   | Group Art Unit         | 1646                     |
|   |   |    |   | Examiner Name          | S. Prasad                |
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|   | AAZ                   | S. GREGORY et al, "Reactive Nitrogen Intermediates Suppress the Primary Immunologic Response to Listeria", J. Immunol., 150 2901 (April 1, 1993)   |                |
|   | BR                    | M. SCHWACHA et al, "Interleukin-12 is Critical for Induction of Nitric Oxide-Mediated Immunosuppression Following Vaccination of Mice with Attenuated Salmonella typhimurium", Infection and Immunity, 65 4897 (December, 1997)                                |                |
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|   | BV                    | J. MACMICKING et al, "Nitric Oxide and Macrophage Function", Annu. Rev. Immunol., 15 323 (1997)  |                |
|   | BW                    | A. KOMAROV et al, "Iron Potentiates Nitric Oxide Scavenging by Dithiocarbamates in Tissue of Septic Shock Mice", Biochim. Biophys. Acta., 1361(3) 229-234 (October 24, 1997)   |                |
|   | BX                    | M. IKEDA et al, "Nitric Oxide Inhibits Intracellular Adhesion Molecule-1 Expression in Rat Mesangial Cells", J. Am. Soc. Nephrol., 7(10) 2213-2218 (October, 1996)   |                |

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|   |   |    |   | Application Number     | 10 079,068               |
|   |   |    |   | Filing Date            | February 20, 2002        |
|   |   |    |   | First Named Inventor   | Giorgio Trinchieri et al |
|   |   |    |   | Group Art Unit         | 1646                     |
|   |   |    |   | Examiner Name          | S. Prasad                |
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|----------------------|----------|--|---|
|                      | BY       | A. HUGHES et al, "Effect of Reactive Oxygen Species on Endothelin-1 Production by Human Mesangial Cells", Kidney Int., 49(1) 181-189 (January, 1996)   |   |
|                      | BZ       | G. TRINCHIERI, "Interleukin-12: A Cytokine by Antigen-Presenting Cells with Immunoregulatory Functions in the Generation of T-Helper Cells Type 1 and Cytotoxic Lymphocytes", Blood, 84 4008 (December 15, 1994)   |   |
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